

REMARKS

Claims 1-15 were pending in the present application. Claims 1-3, 6, 9-11, and 14 have been amended. Claims 4 and 12 have been canceled. Re-examination and reconsideration of pending claims 1-3, 5-11, and 13-15 are respectfully requested.

Independent claim 1 is amended to include the elements of dependent claim 4 and the limitation “such that bronchoconstriction of the airway is reduced.” Support for the added text may be found throughout the specification as filed, for example in paragraphs [0012], [0015], and [0042]. Claim 15 is amended to include the elements of dependent claim 12 as well as the limitation “such that mucus secretions of the airway are reduced.” Support for the added text may be found throughout the specification as filed, for example in paragraph [0028]. The remaining claims have been amended for proper antecedent basis.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

35 USC §102(b) - I

The Office Action rejected claims 1-3, 6-12, 14, and 15 under 35 U.S.C. §102(b) as allegedly being anticipated by Shesterina et al. Applicant disagrees.

First, applicant notes that Shesterina teaches laser treatment with a 0.63- μ m (630 nm) wavelength or a 10.6- μ m (1060 nm) wavelength. See page 2, 5th paragraph; page 3, 1st paragraph. For this reason alone, Shesterina fails to anticipate claims 1 or 10 which now require that the wavelength be in a range of about 240 nm to about 280 nm.

Next, Shesterina teaches “endobronchial laser applications following the methods and principles of reflex therapy.” See page 3, 3rd paragraph. Steadman’s On-Line medical dictionary defines reflex therapy as “treatment of some morbid condition by exciting a reflex action, as in the household treatment of nosebleed by a piece of ice applied to the cervical spine.” In addition, Shesterina states that the “work investigated the possible effect of laser radiation, which also is applied endobronchially to acupuncture points, on the immune status of bronchial-asthma (BA) patients and on individuals with a combination of BA and pulmonary tuberculosis.” See page 1, 3rd paragraph. The acupuncture points “chosen for a session were tailored with consideration for the pathogenetic mechanisms of BA, by the

method of E. D. Tykochinskaya [E. D. Tykochinskaya, *Foundations of Reflex Therapy*, Moscow, 1979] and G. Luvsan [G. Luvsan, *Traditional and Modern Aspects of Eastern Reflex Therapy*, Moscow, 1990].” Shesterina taught use of “one or two acupuncture points with general reflexive action, two with reflexosegmental action, and one or two with regional action.” See page 3, last paragraph.

Significantly, Shesterina explicitly teaches laser application to acupuncture points to produce reflex therapy. Applicant submits that such a disclosure additionally fails to teach or suggest irradiating a length of the airway which causes a change in the airway such that bronchoconstriction of the airway is reduced (claim 1), much less irradiating a length of the airway with a light source which causes a change in the airway such that mucus secretions of the airway are reduced (claim 10).

In view of these several distinctions, applicant requests withdrawal of this rejection with respect to independent claims 1 and 10 (and the claims dependent therefrom).

35 USC §102(b) - II

The Office Action rejected claims 1-3, 5-11, and 13-15 under 35 U.S.C. §102(b) as allegedly being anticipated by Ivanyuta et al. Applicant disagrees that Ivanyuta applies to the claims in the subject application.

First, applicant notes that Ivanyuta teaches laser treatment with a 633 nm wavelength. See page 2, 2nd paragraph. For this reason alone, Ivanyuta fails to anticipate claims 1 or 10 which now require that the wavelength be in a range of about 240 nm to about 280 nm.

More significantly, starting on page 2, Ivanyuta teaches:

The ability of the laser to affect both the pathologic process and immunocompetent cells has been proved. At the same time, the efficacy of endobronchial laser irradiation in chronic bronchitis has received little study, and there are not enough data on the effect of this kind of laser therapy on the state of systemic and local immunity.

Based on the foregoing, we have studied the efficacy of endobronchial low-power laser therapy and its effect on the immune status of patients with chronic nonobstructive bronchitis (CNB) in whom other methods of treatment proved ineffective.

Clearly, this teaching related to CNB additionally fails to teach or suggest irradiating a length of the airway which causes a change in the airway such that bronchoconstriction of the

airway is reduced (claim 1), much less irradiating a length of the airway with a light source which causes a change in the airway such that mucus secretions of the airway are reduced (claim 10).

In view of these several distinctions, applicant requests withdrawal of this rejection with respect to independent claims 1 and 10 (and the claims dependent therefrom).

35 USC §103(a)

The Office Action rejected claims 1-15 under 35 U.S.C. §103(a) as allegedly being unpatentable over James et al. "The Mechanics of Airway Narrowing in Asthma", Am. Rev. Respir. Dis.; Vol. 139; 1989 in combination with U.S. Patent Nos. 5,053,033 to Clarke and 5,574,059 to Regunathan et al. Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness.

Applicant generally notes that patent law clearly requires that the analysis supporting a rejection under 35 U.S.C. 103 must be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Applicant notes that these requirements are made clear in MPEP §2100. In addition, it is well established that when ascertaining the differences between the claimed invention and the cited references, the cited references must be considered as a whole. Applicant submits that in the instant case, by selectively choosing portions of a reference while disregarding other portions of that same reference, the Office Action relies upon impermissible hindsight reconstruction given the benefit of applicant's own invention.

First, as noted in the title itself, James teaches the mechanics of airway narrowing in asthma. Secondly, James concludes on page 246, that the data "suggests that the treatment of asthma should focus on reversing the inflammatory changes in the airway wall an lumen as well as on the relaxation of the smooth muscle." Applicant is unable to find any teaching or suggestion in James of irradiating an airway, much less irradiating a length of the airway which causes a change in the airway such that bronchoconstriction of the airway is reduced (claim 1), or irradiating a length of the airway with a light source which causes a change in the airway such that mucus secretions of the airway are reduced (claim 10).

Next, Clarke addresses reducing proliferation, namely restenosis, of vascular tissue at an angioplasty site. Clarke teaches application of radiation to kill “smooth muscle cells at the site [of an angioplasty]” and expressly states that the application of energy is intended to reduce “the risk of restenosis, while minimizing damage to surrounding tissue.” See col. 2, lines 47-50. Regunathan teaches inhibiting the proliferation of vascular smooth muscle with an I₂ imidazoline receptor agonist for those afflicted with atherosclerosis, restenosis, or traumatic injury to blood vessels. See col. 3, line 61 through col. 4, line 5.

Applicant submits that Clarke and Regunathan merely teach site specific vascular treatments to address areas that experienced previous trauma causing proliferation of tissue (restenosis) rather than treatment to effect a change in the airway’s ability to constrict or to reduce mucus secretion. Clearly, when taking these references together as a whole, applicant submits that one relying on James with Clarke and Regunathan would not apply irradiation to effect a change in the airway’s ability such that bronchoconstrictions or mucus secretions are reduced. Moreover, any suggested combination appears to be based on hindsight reconstruction rather than on the legal requirements of establishing a proper *prima facie* case of obviousness.

Applicant believes that the Office Action fails to establish a proper *prima facie* case of obviousness with respect to independent claims 1 and 10 (and the claims dependent therefrom). Accordingly, applicant requests withdrawal of this rejection.

Nonstatutory, Judicially Created Doctrine of Obvious-Type Double Patenting Rejection

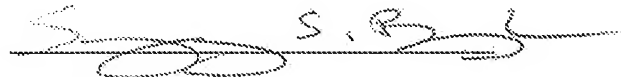
The Office Action provisionally rejected claims 1-15 under U.S. Patent Application No. 09/095,323. Without commenting on the merit of this rejection, applicant is submitting a terminal disclaimer herewith. Accordingly, applicant requests withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. ASTXNA00101. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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